March 2, 2001

National Human Research Protection Advisory Committee (NHRPAC)
Attn: Dr. Greg Koski
6100 Executive Boulevard, Suite 3B01
MSC07507
Rockville, MD 20892-7505

Dear Dr. Koski:

I am writing on behalf of Washington University in St. Louis concerning the Office of Human Research Protection (OHRP) draft interim guidance on the "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subjects Protection." While Washington University supports the spirit of this guidance, we have reservations about the specific provisions included in the guidance.

Washington University and many other leading research institutions are actively engaged in reviewing our conflict of interest policies and the corresponding administrative procedures. This issue is at the forefront of nearly all the professional meetings my staff and I attend, even more so since the August 2000 HHS meeting. Furthermore, I have regular conversations with senior research officers at our peer institutions regarding the future policy direction of financial conflicts of interest, particularly in the area of clinical trials.

Here at Washington University we have established a working group, including the administrative heads of sponsored projects, technology management, clinical studies, and our IRB, which has been assessing our conflict of interest policies and administrative processes. We have identified some potential areas for improvement regarding conflict of interest disclosure coordination between our administrative offices. Our internal recommendations do not include increasing the workload of the already overburdened IRB. The draft interim guidance does in some cases specifically assign additional responsibilities regarding conflict of interest disclosure to the IRB. We feel strongly that any regulatory guidance should allow institutions ample flexibility to develop administrative processes that work in their unique environments.

We have worked hard to develop an institutional policy that mirrors the PHS regulations. The current HHS conflict of interest regulations are not intended to avoid conflicts. Instead, the current regulations recognize that financial conflicts are an inevitable result of many diverse activities within a university. Avoiding conflicts of interest seems to be the goal of the draft interim guidance. Section 2.2 states, "It is desirable to avoid conflicts of interest whenever possible." OHRP should weigh the need for establishing a threshold for financial conflicts of interest in clinical trials that is more stringent than the threshold for other basic research projects.

The draft interim guidance also introduces an area in which regulations are not yet promulgated: institutional conflicts of interest. OHRP, as an advocate of human subjects protection, could add valuable points for consideration. This area is fraught with complexities and many other considerations that will have to be taken into account to capture the institutional obligations. Intense high-level discussions are underway in the university community. I am serving on an AAMC working group on conflict of interest issues, which will convene later this spring. We encourage OHRP to support and engage in this ongoing debate.

I hope you will consider the foregoing suggestions as you consider any changes to PHS' conflict of interest regulations. Thank you for the opportunity to comment on this important issue.

Sincerely yours,

Theodore J. Cicero, Ph.D.
Vice Chancellor for Research